Amendments to the Claims

This listing of claims will replace all prior versions, and listings, of claims in the application.

Listing of Claims

Cancel claims 2-6, 10-14, 19-23, 27-31, 35-39, 45-49, 54-58, and 63-67

Claim 1. (original) An isolated and purified superantigen toxin DNA fragment which has been altered such that binding of the encoded altered toxin to either the MHC class II or T cell antigen receptor is altered.

Claims 2-6. (Cancel without prejudice or disclaimer)

Claim 7. (original) An isolated and purified DNA fragment according to claim 1, wherein said superantigen toxin is toxic shock syndrome toxin-1 having the sequence of SEQ ID NO:11 or a portion thereof, or an allelic portion thereof.

Claim 8. (original) An isolated and purified DNA fragment according to claim 1, wherein said superantigen toxin is Staphylococcal enterotoxin C1 having the sequence of SEQ ID NO:13 or a portion thereof, or an allelic portion thereof.

Claim 9. (original) An isolated and purified DNA fragment according to claim 1, wherein said superantigen toxin is Streptococcal pyrogenic exotoxin A having the sequence of SEQ ID NO:15 or a portion thereof, or an allelic portion thereof.

Claims 10-14. (Cancel without prejudice or disclaimer)

Claim 15. (original) An isolated and purified DNA fragment according to claim 7, wherein said fragment encodes the amino acid sequence of SEQ ID NO:12 or a portion thereof, or an allelic portion thereof.

Claim 16. (original) An isolated and purified DNA fragment according to claim 8, wherein said fragment encodes the amino acid sequence of SEQ ID NO:14 or a portion thereof, or an allelic portion thereof.

Claim 17. (original) An isolated and purified DNA fragment according to claim 9, wherein said fragment encodes the amino acid sequence of SEQ ID NO:16 or a portion thereof, or an allelic portion thereof.

Claim 18. (original) A recombinant DNA construct comprising:

(i) a vector, and

(ii) an isolated and purified altered superantigen toxin DNA fragment according to claim 1.

Claims 19-23. (Cancel without prejudice or disclaimer)

Claim 24. (original) A recombinant DNA construct according to claim 18, wherein said DNA fragment has the sequence according to SEQ ID NO:11 or a portion thereof, or an allelic portion thereof.

Claim 25. (original) A recombinant DNA construct according to claim 18, wherein said DNA fragment has the sequence according to SEQ ID NO:13 or a portion thereof, or an allelic portion thereof.

Claim 26. (original) A recombinant DNA construct according to claim 18, wherein said DNA fragment has the sequence according to SEQ ID NO:15 or a portion thereof, or an allelic portion thereof.

Claims 27-31. (Cancel without prejudice or disclaimer)

Claim 32. (original) The recombinant DNA construct according to claim 24, wherein said DNA fragment encodes the amino acids sequence specified in SEQ ID NO:12.

Claim 33. (original) The recombinant DNA construct according to claim 25, wherein said DNA fragment encodes the amino acids sequence specified in SEQ ID NO:14.

Claim 34. (original) The recombinant DNA construct according to claim 26, wherein said DNA fragment encodes the amino acids sequence specified in SEQ ID NO:16.

Claims 35-39. (Cancel without prejudice or disclaimer)

Claim 40. (original) A recombinant DNA construct according to claim 24 wherein said construct is pETTST30.

Claim 41. (original) A recombinant DNA construct according to claim 25 wherein said construct is pETSEC45.

Claim 42. (original) A recombinant DNA construct according to claim 26 wherein said construct is pETSPEA42.

Claim 43. (original) A recombinant DNA construct according to claim 18, wherein said vector is an expression vector.

Claim 44. (original) A host cell transformed with a recombinant DNA construct according to claim 18.

Claims 45-49. (Cancel without prejudice or disclaimer)

Claim 50. (original) A host cell transformed with a recombinant DNA construct according to claim 32.

Claim 51. (original) A host cell transformed with a recombinant DNA construct according to claim 33.

Claim 52. (original) A host cell transformed with a recombinant DNA construct according to claim 34.

Claim 53. (original) A host cell according to claim 44, wherein said cell is prokaryotic.

Claims 54-58. (Cancel without prejudice or disclaimer)

Claim 59. (original) A host cell according to claim 50, wherein said cell is prokaryotic.

Claim 60. (original) A host cell according to claim 51, wherein said cell is prokaryotic.

Claim 61. (original) A host cell according to claim 52, wherein said cell is prokaryotic.

Claim 62. (original) A method for producing altered superantigen toxin comprising culturing the cells according to claim 44, under conditions such that said DNA fragment is expressed and said superantigen toxin is thereby produced, and isolating said superantigen toxin.

Claims 63-67 (cancel without prejudice or disclaimer)

Claim 68. (original) A method for producing altered superantigen toxin comprising culturing the cells according to claim 50, under conditions such that said DNA fragment is expressed and said superantigen toxin is thereby produced, and isolating said superantigen toxin.

Claim 69. (original) A method for producing altered superantigen toxin comprising culturing the cells according to claim 51, under conditions such that said DNA fragment is expressed and said superantigen toxin is thereby produced, and isolating said superantigen toxin.

Claim 70. (original) A method for producing altered superantigen toxin comprising culturing the cells according to claim 52, under conditions such that said DNA fragment is expressed and said superantigen toxin is thereby produced, and isolating said superantigen toxin.

Claim 71. (original) An isolated and purified superantigen toxin which has been altered such that binding of the encoded altered toxin to either the MHC class II or T cell antigen receptor is altered.

Claim 72. (original) An isolated and purified superantigen toxin according to claim 71 wherein said toxin is staphylococcal enterotoxin A.

Claim 73. (original) An isolated and purified superantigen toxin according to claim 71 wherein said toxin is staphylococcal enterotoxin B.

Claim 74. (original) An isolated and purified superantigen toxin according to claim 71 wherein said toxin is staphylococcal toxin shock syndrome toxin-1.

Claim 75. (original) An isolated and purified superantigen toxin according to claim 71 wherein said toxin is staphylococcal enterotoxin C1.

Claim 76. (original) An altered SEA superantigen toxin peptide according to claim 72 wherein position 92 has been changed to alanine.

Claim 77. (original) An altered SEA superantigen toxin peptide according to claim 72 wherein position 70 has been changed to arginine.

Claim 78. (original) An altered SEA superantigen toxin peptide according to claim 72 wherein position 48 has been changed to arginine.

Claim 79. (original) An altered SEA superantigen toxin peptide according to claim 72 wherein position 64 has been mutated to alanine.

Claim 80. (original) An altered SEB superantigen toxin peptide according to claim 73 wherein position 115 has been changed to alanine.

Claim 81. (original) An altered SEB superantigen toxin peptide according to claim 73 wherein position 89 has been changed to alanine.

Claim 82. (original) An altered SEB superantigen toxin peptide according to claim 73 wherein position 67 has been changed to glutamine.

Claim 83. (original) An altered SEB superantigen toxin peptide according to claim 73 wherein position 94 has been changed to alanine.

Claim 84. (original) An altered SEB superantigen toxin peptide according to claim 73 wherein position 61 has been changed to alanine.

Claim 85. (original) A method for the diagnosis of superantigen-associated bacterial infection comprising the steps of:

(i) contacting a sample from an individual suspected of having a superantigen-associated bacterial infection with altered superantigen toxin; and

(ii) detecting the presence or absence of a superantigen-associated bacterial infection by detecting the presence or absence of a complex formed between the altered superantigen toxin and antibodies specific therefor in the sample.

Claim 86. (original) A method for the diagnosis of a superantigen toxin-associated bacterial infection according to claim 63 wherein the altered superantigen toxin is chosen from the group consisting of SPEa, SEB, SEA, TSST-1, SEC-1.

Claim 87. (original) A superantigen toxin-associated infection diagnostic kit comprising an altered superantigen toxin according to claim 58 wherein said toxin is chosen from the group consisting of SPEa, SEB, SEA, TSST-1, and SEC-1, and ancillary reagents suitable for use in detecting the presence or absence of antibodies against superantigen toxin in a mammalian sample.

Claim 88. (original) A vaccine comprising an altered superantigen toxin according to claim 58 effective for the production of antigenic and immunogenic response resulting in the protection of a mammal against superantigen-associated bacterial infection.

Claim 89. (original) A vaccine according to claim 66 wherein said altered superantigen toxin is chosen from the group consisting of SPEa, SEB, SEA, TSST-1, and SEC-1.

Claim 90. (original) A vaccine according to claim 67 wherein said vaccine further comprises at least one other different altered superantigen toxin chosen from the group consisting of SPEa, SEB, SEA, TSST-1, and SEC-1.

Claim 91. (original) A vaccine according to claim 66, wherein the superantigen toxin is SEB and the vaccine is identified as B899445.

Claim 92. (original) A vaccine according to claim 66, wherein the superantigen toxin is SEA and the vaccine is identified as A489270.

Claim 93. (original) A bivalent vaccine according to claim 68 wherein said altered superantigen toxins are SEA and SEB.

Claim 94. (original) A bivalent vaccine according to claim 71 wherein said toxin SEA is A489270 and SEB is B899445.

Claim 95. (original) A multivalent vaccine against superantigen-associated bacterial infections comprising a combination of altered superantigen toxins selected from the group consisting essentially of TSST-1, SPEa, SEA, SEB, and SEC-1 or any portion or allelic form thereof, capable of eliciting protective antibodies against superantigen toxins in a pharmaceutically acceptable excipient in a pharmaceutically acceptable amount.

Claim 96. (original) A therapeutic method for the treatment or amelioration of a superantigen-associated bacterial infection said method comprising administering to an individual in need of such treatment an effective amount of sera from individuals immunized with one of more altered superantigen toxin vaccine according to claim 67 in a pharmaceutically acceptable dose in a pharmaceutically acceptable excipient.

Claim 97. (original) A therapeutic method for the treatment or amelioration of a superantigen-associated bacterial infection, said method comprising administering to an individual in need of such treatment an effective amount of antibodies against altered

superantigen toxins in a pharmaceutically acceptable dose in a pharmaceutically acceptable excipient.

Claim 98. (original) A therapeutic method for the treatment or amelioration of a superantigen-associated bacterial infection, said method comprising administering to an individual in need of such treatment an effective amount of altered superantigen toxins from streptococcal and staphylococcal bacteria in order to inhibit adhesionof superantigen bacterial toxin to MHC class II or T cell receptors by competitive inhibition of these interactions in a pharmaceutically acceptable dose in a pharmaceutically acceptable excipient.

Claim 99. (original) A therapeutic method for the treatment of diseases that may not be associated directly with superantigen toxins by causing specific nonresponsiveness of T cell subsets or by expanding or stimulating specific T cell subsets, in vivo or ex vivo by use of altered superantigen toxin.

Please add the following new claims 100-102.

Claim 100. (New) The DNA construct designated pETB2360210.

Claim 101. (New) An isolated and purified superantigen toxin DNA fragment encoding Staphylococcal enterotoxin B (SEB) in which at least one amino acid of amino acid positions 40-50 of SEB and at least one amino acid selected from the group consisting of amino acid positions 18-28, 55-65, 62-72, 84-94, 86-96, 89-99, 110-120 and 205-215 of SEB have been altered such that binding of said encoded SEB to the MHC class II receptor and T cell antigen receptor is altered.

Claim 102. (New) The DNA fragment of claim 112, which encodes SEB in which the amino acids in positions 40-50, 84-89 and 89-99 have been altered.